UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 04-61717-CIV-COHN

UNITED STATES OF AMERICA

Plaintiff,

vs.

DR. CHAD LIVDAHL, N.D., DR. ZARAH KARIM, N.D., TOXIN RESEARCH INTERNATIONAL, INC., POWDERZ, INC., THE COSMETIC PHARMACY, INC., and Z SPA, INC.,

Defendants.
_____/

AFFIDAVIT OF FDA SPECIAL AGENT SUSAN J. LEEDS IN SUPPORT OF UNITED STATES' MOTION FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION AND PERMANENT INJUNCTION

The undersigned, Susan J. Leeds, being duly sworn, deposes and states:

1. I am employed as a special agent with the Office of Criminal Investigations ("OCI") of the U.S. Food and Drug Administration ("FDA"). I am responsible for investigating violations of, among others, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "Act").
2. Section 331(a) of Title 21, United States Code, prohibits the introduction into interstate commerce of any drug that is misbranded. Section 321(g)(1) provides in pertinent part: "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than

food) intended to affect the structure or any function of the body of man or other animals . . . .” Section 352(f) of Title 21, United States Code, provides that a drug shall be deemed to be misbranded unless its labeling bears (1) adequate directions for use . . . ” Section 331(d) of Title 21, United States Code, prohibits the introduction or delivery for introduction into interstate commerce a new drug, as defined in 21 U.S.C. § 321(p), unless an approval of an application filed pursuant to 21 U.S.C. § 355 is effective with respect to such drug.

3. According to the FDA, Botulinum Toxin Type A is a drug under 21 U.S.C. § 321(g), when intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, or to affect the structure or the function of the body of man, and a biologic, as defined in the Public Health Service Act, 42 U.S.C. § 262. On December 9, 1991, FDA approved BOTOX®, a drug derived from Botulinum Toxin Type A, manufactured by Allergan of Irvine, California, for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia and the treatment of strabismus and blepharospasm associated with dystonia. On April 12, 2002, FDA approved a supplement to the BOTOX® license application for treatment of glabellular lines, commonly referred to as wrinkles. Under this approval, the supplement is marketed and labeled for this new indication as BOTOX® COSMETIC. According to the FDA, the only Botulinum-derived medications that have been approved for use in the United States by the

FDA are BOTOX® and BOTOX® COSMETIC manufactured by Allergan, and MYOBLOC®, manufactured by Elan Pharmaceuticals.[1] The FDA Center for Drug Evaluation and Research (CDER) does not have a pending application for approval of a product or drug of any kind made or sponsored by any of the defendants in this matter, nor has FDA approved products or drugs of any kind made or sponsored by any of the defendants in this matter.

4. On or about November 30, 2004, OCI initiated an investigation of Advanced Integrated Medical Center, Inc., ("Advanced Integrated"), 1655 E. Oakland Park Boulevard, Fort Lauderdale, Florida, 33334, after four individuals purportedly injected with BOTOX®COSMETIC at Advanced Integrated were hospitalized with symptoms of botulism, on or about November 26, 2004. Three of the four individuals were later confirmed to be suffering from botulism and all four are currently on ventilators.

5. According to the Centers for Disease Control ("CDC"), botulism is a muscle-paralyzing disease caused by a toxin made by a bacterium called *Clostridium botulinum*. Once in the body, the toxin binds to nerve endings at the point where the nerves join muscles. This prevents the nerves from signaling the muscles to contract. The result is weakness and paralysis that descends from the cranium down, affecting, among other things, the muscles that regulate breathing. Recovery can be extremely slow. Assuming the patient receives proper care to ensure continued breathing,

[1] MYOBLOC® is derived from botulinum toxin type B and is approved by the FDA for treatment of patients with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

recovery occurs only when the affected nerves grow new endings, a process that can take several months, although the length of time varies greatly from case to case.

6. According to information obtained by officials of the FDA and CDC from the afflicted individuals, one of the victim's relatives, and an employee of Advanced Integrated, Bach McComb, an osteopathic doctor at Advanced Integrated, had injected himself and the three other victims with purported "Botox" prior to their hospitalization. I subsequently learned that, according to records of the Florida Department of Health, the Florida Department of Health issued an order of emergency suspension of license against McComb to practice as an osteopathic doctor on April 15, 2003, for having allegedly prescribed excessive amounts of controlled substances. Anthony G. Spina, medical malpractice investigator with the Florida Department of Health, confirmed that McComb's license to practice medicine, including dispensing and administration of prescription medicines, is currently suspended. **[Exhibit 1].**

7. On December 1, 2004, I participated in the service of a federal search warrant at the offices of Advanced Integrated. In the course of the search, and pursuant to the warrant, a three-page document from Toxin Research International, Tucson, Arizona ("TRI"), was seized. The first two pages of the document are a "Material Safety Data Sheet" ("MSDS") regarding

Botulinum Neurotoxin Type A.[2] This document states in pertinent part, "Botulinum neurotoxin type A from Clostridium botulinum is a 150,000 dalton protein and is one of the most potent toxins known." The third page of the document, labeled "Product Detail", offers 500 units per vial for $1,250 and two (2) vials for $2,000. It also includes a notation under the company logo which states: "For Research Purposes Only Not For Human Use." **[Exhibit 2].**

8. On December 2, 2004, I reviewed an Order Form printed from the website of Toxin Research International, Inc., www.toxinresearch.com. The form offers one vial, 500 IU/Vial, for $1,250 each, and two vials, 500 IU/Vial, for $1,000 each. Saturday delivery is available upon request. Botulinum Toxin Type A is the only product available for purchase. The form also includes the following statement: "FOR RESEARCH PURPOSES ONLY; NON HUMAN USE ONLY," "ALL SALES ARE FINAL DUE TO DELICATE NATURE OF TOXIN." **[Exhibit 3].**

9. Based on the foregoing and other information obtained in the investigation of Advanced Integrated, I began an investigation of TRI through which I have collected evidence indicating that TRI is offering and selling Botulinum Neurotoxin Type A throughout the United States for use in humans without labeling bearing adequate directions for use, in violation of the provisions of the Act set forth above.

[2] Throughout defendants' promotional materials, invoices, consent forms, and product labeling, TRI uses the terms "Botulinum Toxin Type A" and "Botulinum NeuroToxin Type A," interchangeably. See e.g. Exhibits 2, 8, 9, 10, 12, 16, 17, 19, 20, 21, and 25.

10. According to records on file with the Arizona Corporation Commission, TRI was incorporated in Arizona on May 12, 2003, by Chad Livdahl, N.D., and Zahra Karim, N.D. TRI's Articles of Incorporation list Livdahl and Karim as the corporation's initial Board of Directors, and describe TRI's "Initial Business" as "Toxin distribution & research." The most currently available filings with the Arizona Corporation Commission, dated July 13, 2004, list Chad Livdahl as the President and Chief Executive Officer of the company and the company's principal place of business as 3280 E. Hemisphere Loop, # 116-B, Tucson, Arizona 85706. **[Exhibit 4].**
11. According to records on file with the Arizona Corporation Commission, Powderz, Inc., was incorporated in Arizona on June 12, 2001, by Chad Livdahl, N.D., and its registered agent was listed as Zahra Karim, N.D. Powderz's Articles of Incorporation list Livdahl as the sole member of the company's initial Board of Directors. The most currently available filings with the Arizona Corporation Commission, dated June 3, 2004, list Chad Livdahl as the President of the company and the company's principal place of business as 3280 E. Hemisphere Loop, # 116-A, Tucson, Arizona 85706. **[Exhibit 5].**
12. According to records on file with the Arizona Corporation Commission, The Cosmetic Pharmacy was incorporated in Arizona on June 8, 2004, and its statutory agent of record is Chad Livdahl. The company's principal place of business is listed as 3280 E. Hemisphere Loop, # 112, Tucson, Arizona 85706. **[Exhibit 6].**

13. In furtherance of the investigation, I reviewed an FDA Establishment Inspection Report ("EIR") documenting an inspection of TRI conducted by FDA Consumer Safety Officer ("CSO") Randall Johnson of the FDA's Los Angeles District Office in October 2004. According to the EIR, FDA initiated the inspection upon receiving a complaint from a cosmetic surgeon in Tennessee, who advised the FDA he had been receiving literature from TRI which the doctor believed to be a fraudulent business scheme involving the sale of Botox. During the inspection, TRI provided documents to CSO Johnson indicating a shipment of finished product (the TRI Botulinum Neurotoxin Type A) was received from their contract manufacturer, List Biological Laboratories, Campbell, California. CSO collected the labeling of this product which stated in pertinent part: "TRI TOXIN RESEARCH INTERNATIONAL BOTULINUM NEUROTOXIN TYPE A from Clostridium botulinum 500 IU (mouse LD 50's) 5.0 ng." According to the EIR, Chad Livdahl, who identified himself as the principal owner, operator and President of TRI and Powderz, advised CSO Johnson that TRI is not registered with the FDA and has not filed an IND (Investigational New Drug) or an NDA (New Drug Application) because the product is marketed "for research purposes only, not for human use."

14. In his report, CSO Johnson states he advised Chad Livdahl and Zahra Karim that the Botulinum Toxin Type A of TRI appeared to him to be a drug product. CSO Johnson reported that Livdahl and Karim told him the Botulinum Toxin Type A product is sold only to research institutions and to

licensed physicians conducting research. CSO Johnson's report indicates he informed Karim that use of this Botulinum Toxin Type A on humans or animals for research purposes should bring the product under FDA jurisdiction, requiring compliance with FDA application regulations. Dr. Karim did not respond to CSO Johnson's question regarding whether the physicians purchasing the product were performing their research on humans, animals, or tissue cultures. Dr. Livdahl stated that he did not know whether the researchers were injecting the product after reconstitution, and claimed no specific knowledge of the uses TRI customers might find for the Botulinum Toxin Type A. According to the EIR, Dr. Livdahl refused to allow the FDA to review customer distribution lists during the inspection, claiming confidentiality.

15. On December 4, 2004, I participated in the service of a search warrant at the offices of TRI and Powderz, both found at 3280 Hemisphere Loop, Tucson, Arizona, 85706. During the course of the search, 134 vials, labeled as described above to contain Botulinum Neurotoxin Type A, were located in a refrigerator at TRI and seized. No vials of BOTOX®, or BOTOX® COSMETIC manufactured by Allergan, were located on the premises.

16. During the service of the warrant, OCI agents also seized numerous marketing and registration materials relating to seminars held by the principals of TRI and Powderz, Chad Livdahl and Zahra Karim. These documents reflect Powderz conducted the seminars in July 2003 and

October 2003, and prepared materials for another in September 2004. Included among these documents were:

a. A registration brochure for the July 19-20, 2003, seminar, presented by Powderz, entitled “The Physician’s Approach to Compounding for Aesthetic Enhancement ‘Hands-On’ Workshop and Demonstration,” which advertises a block of instruction from 3:00 p.m. to 4:00 p.m. on July 19, 2003 titled “Botulinum Toxin Type A,” and a block of instruction from 8:00 a.m. to 1:00 p.m. on July 20, 2003, called “Demo/Tutorial Course Botulinum toxin type A, Hyaluronic acid.” **[Exhibit 7].** One of the presenters listed in the July 2003 brochure was Bach McComb, D.O., N.D., Ph.D., whose license to practice medicine was suspended by the Florida Department of Health in April 2003 for having allegedly prescribed excessive amounts of controlled substances. **[Id.; Exhibit 1].**

b. Handwritten consent forms titled “Botulinum Toxin Type A Consent Form and Cross Linked Hyaluronic Acid for Injection,” which appear to be signed by participants at the July seminar, and state as their purpose, “Educational Demonstration.” Several also include in the purpose statement the following: “This is not to be construed to be the practice of medicine.” The consent form lists possible side effects, to include: bruising, redness, droopy eyelid, double vision, pain, and need for more treatment; more or less effect than desired /lumpy appearance, and concludes with the statement, “I agree I

have had the opportunity to ask questions." On a majority of these signed forms, the sentence continues with, ". . . and am having this treatment voluntarily." **[Exhibit 8].** Blank, unexecuted copies of the handwritten consent form were also located and seized. A typewritten version of a consent form, called "Patient Informed Consent," unsigned, was seized. It stated: "This consent form is intended to provide _(Name)_ with the information needed to make an informed decision as to whether or not to undergo Botulinum Toxin Type A (AKA: Botox®, Dysport®, Botulinum Toxin) injection therapy for the treatment of wrinkles, forehead furrowing, frown lines, wrinkling around the eyes, and/or eyelid twitching." **[Exhibit 9].**

c. An agenda for the October 18, 2003, "Powderz Cosmetic Compounding" seminar, which included a 30-minute instruction block called "Botulinum Toxin Type A & Discussion." Notably, a warning regarding Photography/Audio/Visual Taping Restrictions is included in this agenda which reads: "There is strictly no photography, audio, or visual taping allowed. Anyone found photographing or taping without authorization will be required to immediately surrender the film or tape, subject to expulsion, with no reimbursement or further recourse." **[Exhibit 10].**

d. Also single-page disclaimers, which appear to be signed by participants of this October 2003 seminar, state, in part:

> "Powderz disclaims any and all liability for injury or other damages resulting to any individuals attending a session for all claims which may arise out of the use of the techniques demonstrated or discussed therein . . . Some drugs or medical devices demonstrated in Powderz, Inc., courses or described in print or electronic publications have not been cleared by the FDA or have been cleared by the FDA for specific uses only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice." **[Exhibit 11].**

e. Copies of materials for a presentation by The Cosmetic Pharmacy, for a September 18, 2004 seminar labeled "Hands-On Mesotherapy and Cosmetic Techniques Advanced Course." **[Exhibit 12].** Dr. Zahra Karim, NMD is one of three individuals listed on the first page as an instructor. The materials include a section titled, "Botulinum Toxin Type A" and state, "Botulinum Toxin Type A was recently approved for cosmetic use to soften the effects of stress, pollution and aging. It is simply another weapon in our arsenal to significantly enhance a person's appearance thereby boosting their self-image, confidence, satisfaction, & enjoyment of life." There is no mention of BOTOX® or BOTOX® COSMETIC as the only FDA-approved drug derivations of Botulinum Toxin Type A. Several pages with instructions and diagrams for properly injecting the toxin into humans follow. Details as to the amount of units and the amount of injections recommended for each site on the human body are included. Injection points for the upper brow, medial

brow, the forehead, area surrounding the eyes (crow's feet), below the eyes, mouth area, chin, and neck are all diagramed and explained.

17. During the search of TRI's offices, OCI agents also recovered the following records and documents:

    a. A folder labeled "TRI Calls" which contained numerous handwritten notes reflecting names and telephone numbers of physicians throughout the United States. A number of these contacts were accompanied by handwritten notes indicating this contact information applied to doctors and facilities involved in plastic surgery, dermatology, and laser treatments. Also included in the folder was a printout of a testimonial from TRI's website by a Dr. Robert Baker, M.D., which included TRI's posted prices of the Botulinum Toxin type A; specifically, one vial for $1,250 and two vials for $1,000. Handwritten notes on this printout state: "Botox for your wrinkles." **[Exhibit 13]**

    b. A typewritten contact list which contained the names, telephone numbers, addresses and handwritten facsimile numbers of physicians, many of whom are described as ophthalmologists, general surgeons, plastic surgeons and dermatologists. **[Exhibit 14].**

c. An e-mail from Marina Stengart, Registered Nurse, to info@toxinresearch.com, stating her interest in purchasing a vial of TRI's product, asking for a recommendation for the dilution of units per cc and how many milliliters one vial can hold. TRI responds that they will fax Nurse Stengart information on the product, including "how to reconstitute it, and other info." **[Exhibit 15].**

d. A TRI facsimile transmittal sheet, dated February 24, 2004, and addressed to Anita in Dr. Antall's office from Susan at TRI, which states in part: "We received a call from you today about wanting to return our product due to you not noticing that our product is NOT meant for human use. . . . We have clearly marked everywhere you look on our product, website and printed material that it is a research product. We must state that for legal purposes to protect ourselves. Our product is simply Botulinum Toxin Type A which is exactly the same as any Botulinum Toxin Type A that you used in the past. . . . We hope you find some use for our product, and again we apologize but all sales are final." **[Exhibit 16].**

e. Stamped postcards addressed to various physicians advertising "A Very Stable Clostridium Botulinum Toxin Type A" and, in smaller print, the words "For Research Purposes Only Not For Human Use." The postcard also sets forth prices of $1,250 for one 500-IU vial and $1,000 for two 500-IU vials, and provides a coupon offering "$100 OFF your next Purchase." **[Exhibit 17].**

f. A printed copy of an electronic message from “clivdahl” to “Shannon@powderz.com”, dated December 10, 2003, asking Shannon to question the Center for Drug Evaluation and Research (“CDER”) of the FDA whether “we can apply for a generic even though our product does not have the same units as botox (we have 500 per vial and botox has 100), but each unit is equivalent, and we will be submitting studies to demonstrate that 1 unit of their [sp] is equal to 1 unit of ours. . . . Thanks, CHad.” (sic) **[Exhibit 18].**

g. Copies of five (5) invoices, dated December 1 and 2, 2004, and completed order forms for TRI’s Botulinum Neurotoxin Type A, reflecting sales to: Richard Allen, Anthem, Arizona, whose order form includes a copy of a physician’s assistant license in his name; Dr. Robert West at the Almos Heights Skin Clinic in San Antonio, Texas; Dr. Martha Gonzalez, Physician and Surgeon, Ventura California; Dr. Kreg Jenson, Physician and Surgeon, Oren, Utah; and Dr. Herbert Smyczek, Newark, New Jersey. **[Exhibit 19].**

18. On December 6, 2004, I interviewed Thomas M. Toia, whose father, Thomas P. Toia, owns Advanced Integrated. Toia said he has been employed at Advanced Integrated since September 2003, when his father acquired the clinic. Toia was responsible for ordering medical supplies for the clinic, including, at the direction of the doctors, drugs. He stated that on two to four occasions, he ordered vials of Botulinum Toxin Type A from

TRI for Advanced Integrated by telephone. Records indicate sales to Advanced Integrated by TRI on March 11, 2004, April 19, 2004, August 27, 2004, and October 5, 2004, of one quantity of Botulinum Toxin Type A, per order, at $1,250.00 per order, plus $45.00 for UPS Overnight Shipping, for a total of $1,295.00 per order. **[Exhibit 20].**

19. On December 14, 2004, I was informed by an electronic message from OCI Special Agent Tina Stasulli Korb that officials of the New Jersey Department of Health interviewed Dr. Herbert Smyczek, who stated that he had used the TRI Botulinum Toxin Type A on patients. According to Special Agent Korb's message, Dr. Smyczek said he knew the product was not approved for human use, but used it on them anyway.

20. OCI Special Agent Kim Ward advised me that, on December 14, 2004, she spoke by telephone with Dr. Martin Blau, a plastic surgeon in New York. According to Special Agent Ward, Dr. Blau said he believed he purchased Botulinum Toxin Type A from TRI approximately 6 months ago. Dr. Blau stated he received a fax from TRI and called the company. TRI told Dr. Blau that hundreds of physicians were using this product. Dr. Blau said he did not remember seeing the wording "NOT FOR HUMAN USE". He stated he purchased several vials of the product, and used it on himself and his patients. Dr. Blau said he did not experience any problems after using the product and received no complaints from patients who received the injections.

21. I was informed by electronic message from OCI Special Agent Korb that, on December 15, 2004, she spoke by telephone with Dr. Herve Gentile, a plastic surgeon in Corpus Christi, Texas, who said he purchased four vials of the Botulinum Toxin Type A from TRI and had received a great deal of literature from the company. Dr. Gentile stated he also received small cards from Powderz. Dr. Gentile said he used the vials on his wife and two sisters weeks ago and they did not experience any problems, nor did he notice any difference between the Allergan product and that of TRI. Dr. Gentile stated that he disposed of the remaining vials once he read about the Florida case [involving the four patients hospitalized with symptoms of botulism]. He said he did not know the vials were not for human use, and TRI did not tell him that it was not for human use when he spoke to them on the telephone.

22. Commencing on December 15, 2004, OCI Special Agents telephonically interviewed individuals who attended the workshops held by Powderz in July 2003. The individuals contacted included:

    a. Dr. Santos Soberon, who said he and his nurse, Patrise Heiman, attended a cosmetic workshop at the Hyatt Regency in Scottsdale, AZ, on July 19-20, 2003. Dr. Soberon said he learned of the seminar through a mailing he received at his office. Dr. Soberon stated that he spoke with doctors Zahra Karim and Chad Livdahl. The first day of the workshop focused on how to compound Hyaluronic Acid, or “Restylane,” but no injections were

administered. Dr. Soberon said the second day dealt with how to inject Botox and Hyaluronic Acid. Volunteers were injected with the purported "Botox" for wrinkle treatments by Dr. Robert Baker, and Dr. Bach McComb injected volunteers with Hyaluronic Acid. Dr. Soberon stated that he remembered one of the volunteers being Dr. Martha Wilson from San Antonio, Texas. Dr. Soberon stated the vials were labeled "for research purposes – Toxin Research International." He said he never purchased TRI's product, even though it was cheaper than BOTOX® [COSMETIC] from Allergan, because it did not seem to be something they could use in their office. Dr. Soberon's nurse, Patrise Heiman, stated that during the workshop, Dr. Baker made it a point never to use the word "patients," as though he was avoiding it; instead, Dr. Baker used the words, "when you inject your specimens." Heiman stated it was as though Dr. Baker was making it a joke, as if to say, we are not supposed to be using the experimental Botox to inject people, but we'll just keep it to ourselves.

b. Dr. Martha Wilson, from Renaissance Rejuvenation, San Antonio, Texas, who said she attended the conference during July 2003 put on by Powderz. She learned of the conference after receiving an invitation from them regarding the mixing of certain creams. Dr. Wilson said, during the conference, she spoke with the owners of Powderz about the compounding of creams and she also recalled

that they were promoting a Botulinum Toxin that they were manufacturing. The owners of Powderz told the attendees that they could buy the toxin from them at substantially lower prices than Allergan was selling BOTOX® [COSMETIC]. Dr. Wilson recalled that the price for the toxin was about half the price of BOTOX® [COSMETIC]. Dr. Wilson said the instructors at the conference were the owners and a physician who is an Occular Plastic Surgeon at the University of Kentucky and whom she believes is named Dr. Robert Baker. Dr. Wilson said she received an injection of the toxin at the workshop, which had no effect on her. She advised that she is immune to BOTOX® [COSMETIC] and just wanted to see if this version would have an effect on her. The injection she received was administered to her by a doctor, whom she believes was Dr. Baker. She was told before receiving the injection that it was Botulinum Toxin Type A and she recalled seeing the label, which stated "For Animal Use Only." Dr. Wilson said she did not purchase any of the Botulinum Toxin Type A.

c. Dr. James Lowry, of Chicago, Illinois, who recalled attending the Powderz seminar sometime during July 2003. He said he heard about the seminar from Powderz because he bought herbal supplies from them. Dr. Lowry said somebody named Chad from Powderz and other medical doctors did the presentations. Dr. Lowry recalled watching the Botox demonstration. He said the

presenters did not call the product “Botox,” but used some other name he could not remember. He said this product was made by the company and it was something other than Botox. Dr. Lowry did not recall whether the product was for research only, and did not recall seeing the product label of the product. Dr. Lowry did not recall seeing anybody get injected; however, there were “how to” slides presented on how to do the injections on humans. Dr. Lowry said he did not purchase any Botox product from TRI because Botox treatments are far outside his practice and he does not treat those types of patients.

d. Felipe Jimenez, Ph.D., of Visalia, California, recalled attending the Powderz Seminar in Scottsdale, Arizona, during July 2003. Jimenez said they received a flyer for the seminar at the clinic where he works. Jimenez said he was expecting a seminar on compounding hyaluronic acid and collagen injectibles, but they did not get much of that. Jimenez said at the end of the seminar there were Botox demonstrations, where he saw two or three people get injected with a substance specified as Botulinum Toxin Type A. Jimenez said it was emphasized at the seminar that the Botulinum was for research purposes only. Jimenez could not remember what the label looked like. Jimenez stated he thought the doctor doing the injections was a bald male from the Midwest, somewhere like Indiana or Kentucky. Jimenez said he saw no side effects on

the people who received the injections; however, he added that the doctor applied a topical numbing cream before the injection so no side effects would be observable. Jimenez said his clinic purchased Botulinum Toxin from TRI. Jimenez said the first batch they received was not frozen or refrigerated, so they returned it to TRI. TRI sent them an order that was refrigerated and they used this batch on a patient. Jimenez said he could not remember what the labels said. Jimenez said the injected patient called back three or four weeks later and said the injection was ineffective. Jimenez said they gave the patient a free injection of the Allergan product. Jimenez said they sent the remaining TRI product back to TRI because of the experience with this patient.

e. Dr. Ann Murray, of Lake Havascu City, Arizona, who stated she attended the conference in July 2003. During the conference, she was injected with what she believed to be Botulinum Toxin A during a demonstration. She was injected by a nurse, but she did not know her name. She believed it was Botulinum Toxin A because she was told it was “Chad’s Product.” She believed others were also injected with the Botulinum Toxin A, but she could not say how many. Murray did not see the label on the product, nor did she have any adverse reactions. The product was only administered to a small area of her body and it was effective. Dr. Murray said she subsequently purchased Botulinum Toxin A from TRI. She

purchased two vials, by phone, at a cost of $750 and $1,000. She stated that there were no directions for use. The label contained the company name TRI, but she could not recall anything else. Dr. Murray said she used the product on herself and other patients. She did not experience any adverse reactions for any of the treatments. Dr. Murray destroyed her last vial of the product after she heard the news of McComb in south Florida.

f. Dr. William Stephen Martin, of Mobile, Alabama, who stated he attended the compounding seminar in July 2003 after receiving a flyer in the mail regarding the conference. Dr. Martin said, during the conference, he witnessed some seminar participants receive injections of the Botulinum Toxin A from the individuals who put on the workshop. Martin did not see any vials or labeling. During the workshop, it was mentioned that TRI manufactured the Botulinum Toxin A and that it could be purchased for less than the Allergan BOTOX® [COSMETIC]. According to Dr. Martin, they stated the product label would say investigational, not for human use. It was also mentioned at the conference that a doctor from the University of Louisville had been using the product successfully in humans. Dr. Martin said he did not purchase any Botulinum Toxin A from Powderz or TRI.

g. Dr. Helen Donatelli, of the Center for Skin, Vein Laser and Anti-Aging, Sunny Isles, Florida, who said she learned of the July 2003 conference through doctors at her office who received faxes and a flyer in the mail from TRI. Dr. Donatelli said Doctors Zahra Karim and Livdahl were speakers at the conference for the discussion of Botulinum. Dr. Donatelli said she received a certificate for her attendance on July 19, 2003; however, she did not attend the second day of the conference on July 20, 2003. Dr. Donatelli said the syllabus, which she retained, states Dr. Robert Baker and Bach McComb were to speak about Botulinum Toxin on July 20 from 8 a.m. to 9 a.m. and were to conduct a demonstration from 9 a.m. to 10:15 a.m. Dr. Donatelli said Dr. Baker told them their product was more potent than Allergan's BOTOX® [COSMETIC]. Dr. Donatelli recalled them stating it was for research purposes only. Dr. Donatelli said she purchased TRI's Toxin after the conference and used it on herself and her boyfriend's feet, but it did not work or last. Dr. Donatelli said, in January 2004, she met Dr. Baker at the American Academy of Cosmetic Surgery held at the Diplomat Hotel in Hollywood, Florida, where Powderz had a booth. Dr. Donatelli said she talked to Karim at the Powderz booth. During this Florida conference, they told her they could sell her Restylane®,[3] which is

[3] Restylane®, manufactured by Q-Med AB of Sweden, is an injectable gel approved by the FDA on December 12, 2003, for the treatment of facial wrinkles. According to information from the FDA, Restylane®, is made with hyaluronic acid. Handwritten consent forms, which appear to have been signed by attendees of the Powderz July 2003 conference, include a reference to workshop demonstrations of the

hyaluronic acid. The conference flyer said "all substances are FDA approved."

h. Dr. Anya Landeck, of San Rafael, California, who said she attended the conference in the summer of 2003. She stated she learned of the conference though pamphlets mailed to her office. Dr. Landeck said, during the workshop, she witnessed two medical doctors inject patients with TRI's product, Botulinum Toxin A. She stated she did not observe the patients suffer any ill effects. Dr. Landeck said she has purchased several vials of the Botulinum Toxin Type A from TRI over the past few months; it is shipped to her by a private shipping company and has cost $1,250 per 500-IU vial. Dr. Landeck said she orders the product by telephone. Dr. Landeck stated she had one remaining vial of the TRI product and agreed to review the label while speaking with the FDA/OCI agent. Dr. Landeck stated that there were no directions for use on the label. She said the label contained the company name TRI and the words "for research only, not for human use." Landeck stated she has injected herself and patients with the product with no ill effects.

23. During the service of the search warrant at the offices of TRI on December 4, 2004, OCI special agents imaged the data contained within the computers located in the TRI offices. OCI Special Agent Jay Scheurer, a Seized Computer Evidence Recovery Specialist, analyzed the data

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injection of hyaluronic acid, as well as the Botulinum Toxin Type A. This suggests Powderz/TRI may have been injecting hyaluronic acid in July 2003, before any such product was approved for use in the United States by the FDA.

imaged from the TRI computers and determined that, on or about December 1, 2004, a person or person(s) at TRI attempted to delete computer records reflecting the sales of Botulinum Toxin Type A by TRI. Special Agent Scheurer succeeded in retrieving this data, which reflects invoices documenting sales of the Botulinum Toxin Type A within the Southern District of Florida to 13 customers, amounting to 33 invoices, for a total of $53,211.15 (Affidavit, ¶ 23). **[Exhibit 21].**

24. In the course of conducting the search at the offices of TRI on December 4, 2004, OCI agents located documents concerning an entity called Z Spa, Inc. Records of the Arizona Corporation Commission reflect that Z Spa, Inc. ("Z Spa") was incorporated on February 13, 2004, and maintains its offices at 3280 E. Hemisphere Loop, Suite 116-E, Tucson, Arizona, the same suite of offices in which TRI and Powderz are located. The statutory agent listed in the corporate documents filed with the Arizona Corporation Commission is Chad Livdahl. **[Exhibit 22]**

25. Among the documents recovered at the search of TRI was a fax from Vern Holmquist, which purports to pertain to "Zspa, Inc.," and accompanies a one page document which appears to be a proposed endorsement to an insurance policy **[Exhibit 23].** At the top of the page are the words, "AMENDATORY EXCLUSION – BOTOX." On February 14, 2004, I telephoned Mr. Holmquist, who told me he is President of Pinnacle Insurance Agency, Inc., Scottsdale, Arizona, and has written insurance policies for Powderz. He stated he discussed Z Spa with Livdahl and

Karim in May 2004, and then heard nothing more until approximately two weeks prior to my conversation with him, when he said the doctors called and said they were about ready to go with Z Spa. He faxed the endorsement to them at that time. Mr. Holmquist said he understood Botox treatments would be provided at Z Spa.

26. Also located during the search of TRI's offices was a six-page fax from Almond A D G, Inc. ("Almond"), Scottsdale, Arizona, to TRI and addressed to the attention of Chad Livdahl and Zahra Karim. Attached to the coversheet was an invoice in the amount of $3,500.00 from Almond to TRI, dated December 1, 2004 and stamped "PAID." The description of services rendered states: "Payment in full for the design and construction documents phase of the project per the contract dated 12-1-04." **[Exhibit 24].** Attached to the invoice is a letter from Almond to Livdahl and Karim, dated December 1, 2004. The first sentence of the letter states: "The following is a proposal to provide Architectural/Engineering Services of a Tenant Improvement for 'Z' Spa proposed at Gainey Village, Scottsdale, Arizona." Under the heading, "SCOPE OF PROJECT," the letter states: "Convert a Cold Stone Creamery space into approximately 1,200 square feet for treatment rooms, consult, reception, administrative areas, and (1) restroom. Interior work only. No exterior improvements." **[Id.]**

27. On December 18, 2004, I reviewed the Internet website of Z Spa, located at www.z-spa.net **(Exhibit 25].**[4] The website states that Z Spa is currently located at 4380 N. Campbell Avenue, Suite 201 (no city provided), and further states: "Coming Soon: Z-Spa at Scottsdale Gainey Village." On its website, Z Spa purports to have "the most advanced Anti-aging Skin Care Treatments available . . . ", and lists "Botox®" and "Restylane® & Collagen." The website also publicizes an "Open House" at Z Spa scheduled for January 15 and 16, 2005, at the N. Campbell Avenue location, where, according to the website, patrons can expect "Free Education on the latest cosmetic treatments available."

28. On December 20, 2004, I reviewed TRI's website at www.toxinresearch.com. The web-site was still up and running, and the link to the Order Form was still operational. Also, on December 20, 2004, I placed a telephone call to the toll-free number listed on the TRI order form. A female voice on an answering machine identified the number that I dialed as that of "Toxin Research International," and stated that I could dial the extension of the person to whom I wanted to speak if I knew it, and if not, invited me to leave a message in the general mailbox.

[4] The website shows the name of the company as "Z Spa," "Zspa," as well as "Z-Spa."

Pursuant to Title 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing Affidavit in Support of United States' Motion for Temporary Restraining Order, Preliminary and Permanent Injunction brought against defendants, Dr. Chad Livdahl, N.D, Dr. Zarah Karim, N.D., Toxin Research International, Inc., Powderz, Inc., The Cosmetic Pharmacy, Inc., and Z Spa, Inc., is true and correct to the best of my knowledge.

Executed this_____ day of December, 2004.

_____
Susan J. Leeds
Special Agent
U.S. Food and Drug Administration
Office of Criminal Investigations

Sworn to and Subscribed before me this
_____ day of December, 2004

_____
Notary Republic

My commission expires: